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FILED

DECEMBER 5, 2005

NEW JERSEY STATE BOARD OF MEDICAL EXAMINERS

STATE OF NEW JERSEY
DEPARTMENT OF LAW & PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
STATE BOARD OF MEDICAL EXAMINERS

IN THE MATTER OF THE SUSPENSION OR REVOCATION OF THE LICENSE OF

Administrative Action

HERBERT S. SMYCZEK, M.D.

CONSENT ORDER

TO PRACTICE MEDICINE IN THE STATE OF NEW JERSEY

This matter was most recently opened to the State Board of Medical Examiners (Board) upon notice from the Department of Health of the City of Newark that it had undertaken an investigation of the doctor's medical practice in that city. In a joint investigation among the Board, the City of Newark, and the State Department of Health, it became known that Dr. Smyczek had purchased and administered to three of his patients, Botulinum Toxin which was unapproved for human use. There was no report that any of the patients suffered any harm.

CERTIFIED TRUE COPY

The doctor cooperated in the investigation and appeared before a Committee of the Board in March 2005 together with his counsel, Michael Schoppmann, Esq. and Donna Mantel, Esq. According to the doctor's testimony, during a seminar on bio-identical hormone replacement which he attended in November 2004, he was advised of the availability of a generic "Botox" which was less expensive than the brand name Botox. It was his intention to obtain the so-called "generic Botox" for administration to his patients at a satellite office he maintained at the Ndulge Spa in Palmyra, New Jersey. He arranged for the delivery of the product and upon its receipt realized that it did not have FDA approval for human use. After a conversation with a manufacturer's representative, the doctor decided to administer the Botox to his patients despite its unapproved status. He administered the unapproved drug to three patients in December 2004. Subsequently, growing concerned about possible side effects of unapproved Botulinum Toxin, he remained in contact with those patients to ensure that they suffered no adverse effects.

At the time of his testimony, the doctor acknowledged that he used poor judgment in obtaining and administering the unapproved Botulinum Toxin. He testified that he was naive in his assessment of the information provided at the seminar and was personally devastated by the potential risk to the public caused by his foolhardy and irresponsible actions.

The doctor discussed the nature of his private practice at length with the members of the Board Committee. In particular, he

advised that he no longer practices at a satellite location but restricts his practice to his Newark based office. Further, he willingly accepted Committee guidance with regard to improvements required in his record keeping as well as the need to maintain certain emergency recessitative equipment on site. The Board views the doctor's cooperation in the investigation and the changes in his practice as mitigating information. Nonetheless, the Board finds that the doctor has engaged in both professional misconduct and gross negligence.

The Board finding the within disposition is adequately protective of the public health, safety and welfare,

IT IS on this 5TH day of DECEMBER 2005:

ORDERED:

- 1. Herbert S. Smyczek, M.D. is hereby reprimanded for the conduct set forth herein.
- 2. Dr. Herbert Smyczek shall enroll in and successfully complete a Board-approved medical ethics course, at his own expense, within twelve (12) months of the entry of this Order. Said course must be approved by the Medical Education Director of the Board prior to enrollment and proof of completion of and an unconditional passing grade in said course shall be sent to the New Jersey State Board of Medical Examiners, P.O. Box 183, Trenton, New Jersey 08625-0183 no later than thirty (30) days from receipt of said proof.
- 3. Dr. Herbert Smyczek shall pay a penalty in the amount of \$5,000.00 upon execution of the within Order.

- 4. Dr. Herbert Smyczek shall pay investigative costs in the amount of \$2,461.00 upon execution of the within Order.
- 5. Dr. Herbert Smyczek shall enroll in and successfully complete eight continuing medical education credits and they shall be approved in advance by the Medical Education Director of the Board (in addition to the regulatory requirement set forth in N.J.A.C. 13:35-6.15).
- 6. Dr. Herbert Smyczek shall refrain from undertaking his own medical care and place himself in the care of another individual to serve as his personal physician.

7. Dr. Herbert Smyczek shall take all steps necessary to Insure that his advertisements and telephone directory listings are in complete compliance with the requirements of the Board's statutes and regulations.

STATE BOARD OF MEDICAL EXAMINERS

Dr. Bernard Robins, M.D. President

I have read and understand the contents of the within Consent Order and agree to be bound by its terms.

Herbert S. Smyczek, M.D.

70 Consented/as to form:

Donna Mantel, Esq.